

### **REMARKS**

Claims 1-33 are presently pending in this application. Claims 6, 9, 12, and 14 have been amended. Therefore, claims 1-33 remain pending in the present application.

#### **In the Specification**

The Applicants previously claimed priority back to Application No. 60/421,626, which was filed on October 29, 2002, in the declaration. See Exhibit 1. The declaration was submitted within the time period set forth in 37 C.F.R. 1.78(a). The Patent Office acknowledged priority to Application No. 60/421,626 in its filing receipt. See Exhibit 2. The Applicants inadvertently did not include the claimed priority in the first sentence of the specification. The Applicants have added a Cross-Reference to Related Application Section that includes the claimed priority to Application No. 60/421,626 as the first sentence of the specification. Pursuant to MPEP 201.11, since the declaration was timely filed and the information concerning the benefit claim was recognized by the Patent Office as shown by its inclusion on the first filing receipt, a petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Therefore, the Applicants respectfully request that the Cross-Reference to Related Application Section be added to the present application.

#### **Information Disclosure Statement**

The Applicants are concurrently submitting a Second Information Disclosure Statement. The Applicants respectfully request that the Examiner review these references and make them of record.

#### **Claim Rejections - 35 U.S.C. § 103 – Kurandt in View of Admitted Prior Art**

Claims 1-3 and 7-8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,838,697 to Kurandt (“Kurandt”) in view of the Applicants’ Admitted Prior Art (“A.P.A.”).

##### **Independent Claim 1**

It is the Applicants’ belief that a *prima facie* case of obviousness has not been presented. To establish a *prima facie* case of obviousness, three criteria must be met. First, there must be a suggestion or motivation within the references themselves to combine the art. Second, there must

be a reasonable expectation of success. Third, the references, when combined, must teach **all** of the claim limitations. MPEP § 2142. It is the Applicants' belief that the criteria has not been satisfied.

The Office Action is apparently applying the A.P.A. to account for deficiencies in Kurandt, which the Applicants submit is improper. First, the A.P.A. cited by the Office Action merely discusses the problems with the "[c]urrent methods of diffuse reflectance using LEDs as a monochromatic source of illumination" that the present invention attempts to solve. Present Spec., p. 3, ll. 23-24. Specifically, the cited A.P.A. states that "the problem with using an LED having a typical center wavelength tolerance of plus or minus 20nm causes a variation in the diffused reflectance." *Id.*, p. 3, ll. 24-25. Nowhere in the cited A.P.A., or anywhere else in the A.P.A., are the limitations of claim 1 disclosed, taught, or suggested.

Furthermore, even accepting the Office Action's statement that "it is well known for filter/LED to have a tolerance as evident by the applicant's disclosure" as true (which the Applicants submit is improper), it is entirely unclear how the limitations of claim 1 requiring that "the filter tolerance is **no greater than approximately one-half** the illumination tolerance" and "the filter center-wavelength is approximately within a range from about **the illumination center-wavelength minus the illumination tolerance to about the illumination center-wavelength plus the illumination tolerance**" would be obvious. The Applicants respectfully submit that such a leap in logic was made only after reading the disclosure of the present invention. Thus, the Applicants respectfully submit that the rejection of claim 1 was based on impermissible hindsight reconstruction.

Thus, when Kurandt is combined with the A.P.A., all of the limitations of claim 1 are not present. As such, the Applicants respectfully submit that independent claim 1 and its dependent claims 2-8 are patentable over Kurandt in view of the A.P.A.

### **Dependent Claims 2 and 8**

The Applicants submit that the Examiner must consider the teachings of the cited references in their entirety, including disclosures that teach away from the present claims. MPEP § 2145. The Office Action correctly states that the A.P.A. discloses current methods of reading diffuse reflectance using LEDs having a typical center wavelength tolerance of plus or minus 20nm. Office Action, p. 3; Present Spec., p. 3, ll. 23-26. However, the purpose of the cited A.P.A. is to discuss **disadvantages** associated with such LEDs:

The problem with using an LED is that a typical center wavelength tolerance of plus or minus 20nm causes a variation in the diffused reflectance. The variation in wavelength around the center wavelength will cause the reagent color to vary around a reflectance corresponding to the center wavelength of the LED. This reflectance variation translates into an error in glucose concentration. An error in glucose concentration level can lead the user to take too much medicine or avoid taking enough medicine, thereby resulting in a potential seizure, coma, or even death.

Present Spec., p. 3, ll. 24-31. Thus, the A.P.A. actually **teaches away** from using an LED having a typical center wavelength tolerance of plus or minus 20nm, as required by claims 2 and 8. Therefore, a skilled artisan, after reading the cited A.P.A., would not have been motivated to modify Kurandt to utilize an LED having a typical center wavelength tolerance of plus or minus 20nm, as set forth in claims 2 and 8.

Thus, a *prima facie* case of obviousness has not been established because the cited A.P.A. teaches away from the present invention. For these reasons as well as for the reasons set forth above with respect to claim 1, from which claims 2 and 8 depend, the Applicants respectfully submit that claims 2 and 8 are not obvious in view of Kurandt in view of the A.P.A.

#### **Claims 6 and 7**

The Applicants respectfully submit that a *prima facie* case of obviousness has not been made with respect to claims 6 and 7 because the applied references do not disclose, teach, or suggest all of the elements of claims 6 and 7. Claim 6 requires that “the first illumination source is an LED comprising an associated illumination center-wavelength is approximately within a range from about 680nm to about 960nm.” Claim 7 requires that “the illumination center-wavelength associated with the first illumination source is approximately within a range from about 700nm to about 740nm” and “the illumination center-wavelength associated with the second illumination source is approximately within a range from about 510nm to about 550nm.”

Nowhere in Kurandt, the A.P.A., or a combination thereof are these ranges disclosed, taught, or suggested. Specifically, the LEDs of Kurandt irradiate in the blue spectral range having an illumination center-wavelength at 480nm, the green spectral range having an illumination center-wavelength at 555nm, and the red spectral range having an illumination center-wavelength at 670nm. Kurandt, col. 2, ll. 60-65.

Thus, because none of the LEDs disclosed in Kurandt falls within the ranges of claims 6 and 7 recited above, and because of the reasons set forth with respect to claim 1 from which claims 2 and 8 depend, the Applicants respectfully request that the Examiner withdraw the rejection of claims 6 and 7.

**Claim Rejections - 35 U.S.C. § 103 – Kurandt in View of Henderson**

Claims 9-32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kurandt in view of U.S. Patent No. 3,910,701 to Henderson et al. (“Henderson”).

**Independent Claims 9 and 14**

The Applicants respectfully submit that a *prima facie* case of obviousness has not been made because the proposed combination fails to teach all of the elements of independent claims 9 and 14. Claims 9 and 14 require a beam splitter that has a bandpass filter wherein “the bandpass filter comprises a relatively narrow bandpass compared to a bandwidth associated with the first LED . . . .”

The Office Action acknowledges that “Kurandt is silent regarding to the dimensions/degrees of filter tolerance and the bandpass filter comprising a relatively narrow bandpass as compared to a bandwidth associated with the first LED.” Office Action, p. 4. To support his assertion that this limitation is taught by Henderson, the Office Action has relied on the following: “such reflectance measurements can presently be obtained by instruments known as reflectometers. These devices can measure the amplitude of light-reflectance at any selected narrow band of light . . . .” Henderson, col. 2, ll. 12-16; Office Action, p. 4. This portion of Henderson merely describes a general reflectometer, and the portion immediately following describes the drawbacks and limitations of reflectometers. *Id.* at col. 2, ll. 18-31. Nowhere in Henderson, Kurandt, or a combination thereof is “a relatively narrow bandpass as compared to a bandwidth associated with the first LED” disclosed, suggested, or taught, let alone a bandpass filter having such a relatively narrow bandpass.

Furthermore, it is unclear what the Office Action is referring to in stating that it would have been obvious to incorporate the teachings of Kurandt “with applicant indication of feature to design/provide readhead with a various tolerance to meet the terms of the claims”. If this rejection is maintained, the Applicants respectfully request that the subsequent Office Action clarify where,

either in the references, the Applicants' disclosure, or knowledge generally available to one of ordinary skill in the art, such limitations as are disclosed in claims 9 and 14 are suggested so that the Applicants may evaluate such a statement.

Thus, for at least these reasons, the Applicants respectfully submit that independent claims 9 and 14 and claims 10-13 and 15-22, which depend from claim 9 or claim 14, respectively, are allowable over Kurandt in view of Henderson.

#### **Claim 10**

Claim 10, which depends from claim 9, requires that "the bandwidth associated with the first LED is approximately 100nm; and the narrow bandpass is approximately 25nm." In support of the Office Action's statement that "Henderson discloses a variety of wavelengths (i.e. 100nm) and any selected narrow band (i.e. 25nm)", the Office Action at page 5 has cited the following portions of Henderson: ". . . such reflectance measurements can presently be obtained by instruments known as reflectometers. These devices can measure the amplitude of light-reflectance at any selected narrow band of light . . .", Henderson, col. 2, ll. 12-16, and "Light emitting diodes are now available in a wide variety of wavelengths, and each of modules 13, 14 and 15 can be provided with various combinations of wavelengths selected from the following representative list of wavelengths [ranging from 570nm to 940nm] offered by LED manufacturers", *id.* at col. 6, ll. 18-22. The Applicants respectfully submit that neither the cited portion, nor any other portion of Henderson discloses, teaches, or suggests the specific limitations of claim 10.

Thus, for at least these reasons, as well as for those reasons provided above with respect to claim 9, from which claim 10 depends, the Applicants submit that claim 10 is not obvious over Kurandt in view of Henderson.

#### **Claim 11**

Claim 11, which depends from claim 9, requires that "the first and second LEDs have associated tolerances **not greater than 20nm** and the bandpass filter has an associated tolerance of not greater than 10nm." The Office Action has relied on a portion of the present specification stating, "The problem with using an LED is that a typical center wavelength tolerance of plus or minus 20nm causes a variation in the diffused reflectance" to support his assertion that this limitation that this limitation is well known. The Applicants respectfully submit, however, that an

associated tolerance “not greater than 20nm”, as required by claim 11, is **not** the same as or an obvious variation of a tolerance of “plus or minus 20nm,” as disclosed by the A.P.A. Furthermore, no where in the cited A.P.A. is the limitation of a “bandpass filter has an associated tolerance of not greater than 10nm” disclosed, taught, or suggested.

Thus, the Applicants submit that claim 11 is allowable for at least these reasons and the reasons provided above with respect to claim 9.

### **Claims 12-13, 23, and 25**

Claims 12 and 23 require a “light-scattering section [that] comprises a plurality of steps” having “angles greater than 90 degrees.” Claim 13, which depends from claim 12, further requires that the “angles at which the steps are formed are not less than approximately 100 degrees.” Claim 25 requires that “the one or more angles defined by the plurality of steps are approximately 100 degrees.”

In support of his assertion that claims 12-13, 23, and 25 are obvious, the Office Action generally cites only to the figures of the cited references. The Office Action has not specifically identified where in either of the references or figures thereof or in knowledge generally available to one skilled in the art, such limitations are disclosed, taught, or suggested. If this rejection is maintained, the Applicants respectfully request that the subsequent Office Action clarify where, either in the references, the Applicants’ disclosure, or knowledge generally available to one of ordinary skill in the art, such limitations as are disclosed in claims 12-13, 23, and 25 are suggested so that the Applicants may evaluate such a statement.

Thus, the Applicants respectfully submit that claims 12 and 35 are allowable and respectfully request that the Examiner withdraw the rejection.

### **Claims 21 and 32**

Claim 21, which depends from claims 14 and 19-20, requires that “the filter tolerance is not greater than about 10nm.” Claim 32, which depends from claims 28-30, requires that “the filter center-wavelength is less than approximately the first center-wavelength minus 20nm.”

The Office Action has not identified where in either of the references or in knowledge generally available to one skilled in the art, the limitations of claims 21 and 32 are disclosed, taught, or suggested. If this rejection is maintained, the Applicants respectfully request that the subsequent

Office Action clarify where, either in the references, the Applicants' disclosure, or knowledge generally available to one of ordinary skill in the art, such limitations as are disclosed in claims 21 and 32 are suggested so that the Applicants may evaluate such a statement.

Thus, for these reasons as well as for those provided with respect to the claims 14 and 28 from which claims 21 and 32 depend, respectively, the Applicants respectfully submit that claims 21 and 32 are allowable.

#### **Independent Claim 24**

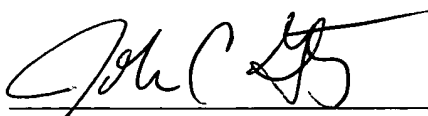
The Applicants respectfully submit that independent claim 24 is allowable for at least the same reasons as set forth above with respect to claims 9 and 14 and claims 12-13, 23, and 25. Applicants further submit that claims 25-33, which depend from claim 24, are allowable for at least the same reasons.

#### **Conclusion**

Applicants submit that the claims are in a condition for allowance and action toward that end is earnestly solicited. A check in the amount of \$180.00 is enclosed for the Second Information Disclosure Statement. Applicants do not believe that any additional fees are due; however, should any additional fees be required (except for payment of the issue fee), the Commissioner is authorized to deduct the fees from Bayer HealthCare LLC Deposit Account No. 13-3375 (MSE-2673).

Dated: June 21, 2006

Respectfully submitted,



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